Wirral Community NHS
NHS Trust

STANDARD OPERATING PROCEDURE

USE OF POINT OF CARE TESTING DEVICE: COAGUCHEK XS PLUS FOR ALL TRUST STAFF

Issue History	Issue Version	Purpose of Issue/Description of Change	Planned Review Date
	One	To ensure safe point of care testing, using the CoaguChek XS Plus machine, resulting in an accurate INR	2018

Named Responsible Officer:-	Approved by	Date
Medicines Governance Pharmacist	Quality, Patient Experience, and Risk Group	March 2015
Section:- Medicines Management **MMSOP45**	**Target Audience** All trust staff who use the CoaguChek XS Plus machine as part of their job role	

UNLESS THIS VERSION HAS BEEN TAKEN DIRECTLY FROM TRUST WEB SITE THERE IS NO ASSURANCE THIS IS THE CORRECT VERSION

CONTROL RECORD			
Title	Standard Operating Procedure for the use of point of care testing device CoaguChek XS Plus		
Purpose	To ensure safe point of care testing, using the CoaguChek XS Plus machine, resulting in an accurate INR.		
Author	Quality and Governance Service (QGS) J Edwards		
Impact Assessment	Incorporated into procedure	**Yes**	No
Subject Experts	Trust Pharmacist		
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Groups consulted with :-	N/A		
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VERSION CONTROL RECORD		
Author	**Status**	**Changes / Comments**
J Edwards/	N	

Status – New / Revised / Trust Change

NAME OF DISCIPLINE: PRIMARY CARE	
OBJECTIVES	To ensure safe point of care testing, using the CoaguChek XS Plus machine, resulting in an accurate INR. .
SCOPE	The purpose of this document is to: • Cover all aspects of point of care testing inclusive of internal and external quality control testing • Ensure accurate documentation inclusive of patients record and OAT (Oral Anticoagulation Therapy) book • Ensure safe storage of machine and consumables as per manufacturer's recommendations. • Ensure strips and quality control medium are in date and the code chip number of test strip is recorded in meter for each patient test To be read in conjunction with the CoaguChek XS Plus Operator's Manual. This document does not provide guidance on the: • Use of computer decision dosing software – please refer to the manufacturers user manual. • Management of high INRs – for information refer to the Wirral High INR Pathway for GP practices or departmental guidance for the DVT Service only
TARGET GROUP (Staff authorised to follow this SOP)	All trust staff who have undertaken appropriate training and assessment to competently use the CoaguChek XS Plus machine.
EVIDENCE TO SUPPORT PROCEDURE	NPSA alert 18 2006 Wirral Anticoagulant (Oral) Therapy Prescribing Guidelines 2012 CoaguChek XS Plus Operator's Manual
RELATED POLICIES	Please refer to relevant Trust policies and procedures Wirral CCG Anticoagulation Enhanced Service Agreement (if appropriate)
IT IS THE RESPONSIBITITY OF ALL STAFF TO COMPLY WITH RELEVANT TRUST POLICIES, PROCEDURES AND PROTOCOLS IN CONJUNCTION WITH THIS PROCEDURE	

Procedure		
Activity	**Rationale**	**Responsibility**
1.Quality Control		
Internal Quality Control (IQC) Perform IQC weekly as per manufacturer's instructions (see operator's manual) and also consider if INR appears out of range for a specific patient. Manufacturers' recommendations on storage must be adhered to. Document the results in the quality control recording log.	To ensure accuracy and performance of meter and provide an audit trail for the future	Designated user: (General Practitioner, Practice Nurse, Health Care Assistant Advanced Nurse Practitioner, Nurse Practitioner)
External Quality Control (EQC) All practices providing Point of Care testing must have registered with National External Quality Assurance Scheme (NEQAS) Perform EQC as per manufacturer's instructions when instructed via NEQAS Participating centres in the INR programmes will be sent four surveys per year, each comprising two samples for INR determination. Participants will be provided with instructions on reconstitution and testing of the samples. Results will be analysed, and individual reports sent to participants approximately one week after the closing date of a survey.	To ensure external monitoring of device and comparison with other centres using the same device	Designated user
2. Performing capillary blood sample INR		
At the initial appointment on outlining the Point Of Care Testing (POCT) service, explain procedure to patient and obtain informed consent, document in the patient's record. N.B. POCT INRs have been shown to be unreliable in patients with antiphospholipid antibodies and their use is not recommended in this group of patients.	To allow the patient to make an informed decision and gain co-operation	Designated user performing sample taking
Check that quality control test has been performed within recommended time limits.	To ensure meter is functioning correctly	Designated user performing sample taking.
Advise patient to wash their hands prior to procedure – assist if necessary Alcohol gel may be used but ensure gel is dry before completing test	To prevent sample contamination and warm patients hands to improve blood circulation	Designated user performing sample taking.
The designated user must prepare the single use disposable lancet device as per manufacturer's instructions.	To ensure correct use of equipment	Designated user performing sample taking.
Switch the meter on, press patient test button, input patient ID number or add if a new patient.	To ensure the correct patient identified before proceeding with test	Designated user performing sample taking.

Check meter and test strip code match, remove new test strip from vial, replace lid tightly.	To ensure meter is calibrated to test strip and to prevent deterioration of remaining strips	Designated user performing sample taking.
Slide test strip into test strip guide with lettering facing upwards a beep tone will indicate the meter has detected the strip **A blood drop icon will flash to indicate the meter is ready to accept the blood sample**	To ensure the test strip is inserted correctly	Designated user performing sample taking.
Decontaminate hands	To remove any accumulated transient skin flora that may have built up under the gloves or acquired during the procedure	Designated user performing sample taking.
Apply single use disposable non sterile gloves	To protect hands from contamination with organic matter and transfer of micro-organisms	Designated user performing sample taking.
Using the disposable lancet obtain a blood sample from the side of the finger, massage the lanced finger until a drop of blood is formed. **Do not press or squeeze the finger**	Side of finger is a less painful site to use To ensure an accurate result.	Designated user performing sample taking.
Apply one drop of blood directly to the semicircular transparent area of the test strip **OR** you can touch the blood drop against the side of the sample area making sure to hold the blood drop to the strip until the flashing blood drop icon has disappeared	The test strip draws up the blood by capillary action	Designated user performing sample taking.
Apply the blood drop to the test strip within **15 seconds** of lancing the fingertip	To prevent false results due to the coagulation process already beginning	Designated user performing sample taking
Dispose of used lancet into sharps container	To reduce the risk of innoculation injury	Designated user performing sample taking
The meter will perform an automatic quality control test on test strip before it displays test result QC will appear in the display	To ensure accuracy of test.	Designated user performing sample taking
The INR result will be displayed and saved to memory Repeat the test if the result is **unexplained** e.g. below 1.5 or greater than 5.	To enable user of the meter to interpret result, document in patient notes and computer decision support software	Designated user performing sample taking
On completion of procedure remove: • the test strip from the measurement chamber • personal protective equipment (PPE).	To prevent cross infection and environmental contamination	Designated user performing sample taking

and dispose of appropriately.		
Decontaminate hands	To remove any accumulated transient skin flora that may have built up under the gloves or acquired during the procedure	Designated user performing sample taking
Turn the meter off and clean as per manufacturer's guidance	To prevent cross infection or contamination of further tests	Designated user performing sample taking
3.Documentation		
Document all actions observations and INR result (including consent) in the patient's record and in the Oral Anticoagulation Therapy (OAT) book (yellow book).	Ensure compliance with NMC/GMC and local record keeping guidelines	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
If available, input INR result into Clinical Decision Support Software (CDSS) e.g. INR Star	To enable Clinician to provide warfarin dose information to be discussed with patient	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
Explain results to patient and any necessary action needed. Document all discussions/actions in clinical systems and OAT book (yellow book) Ensure the next appointment is given to the patient If CDSS is used: Ensure that the patient is given the printed diary from INR Star, detailing their result and dosage schedule for each day prior to their next appointment, as well as details of their next appointment Keep a printed file copy of the patient's dosing diary as a backup in case of IT systems failure	Patient to be fully informed of actions and potential changes to treatment in order to give informed consent	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
4.Special considerations		
If any clinical concerns arise regarding the management of the patient or if INR levels are outside of target range; discuss with General Practitioner or authorised prescriber responsible for the patient on the same day as test undertaken and refer to Wirral Anticoagulant (Oral) Therapy Prescribing Guidelines	To ensure patient safety and correct management of patients on anticoagulation therapy	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
The clinician managing the patient should ensure that all relevant information has been sought from the patient on assessment e.g. • General status of patient Has the patient: • Had any recent bruising or bleeding	To ensure patient safety and correct management of patients on anticoagulation therapy	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose

• Had a recent fall or any other impact injury • Any change in medication or diet • Commenced any over the counter (OTC) medications • Been compliant with warfarin dosing schedule • Understood the information given to them at last appointment See appendix 1 for more information relating to this.		
Failure of machine to produce results. Meter will not register an INR of above 8 A venous blood sample will be required for laboratory INR Following discussions with the identified service anticoagulation lead, ensure collection of a venous blood sample and further dosing as per Lab results.	To ensure patient safety and correct management of patients on anticoagulation therapy	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
All services participating in INR monitoring are required to maintain a stock of Konakion® MM Paediatric 2mg/0.2mL ampoules for administration to patients with an INR >=8 who do not have major bleeding, The decision to administer Konakion should be made by a clinician (doctor or nurse) with the appropriate knowledge & training, following the High INR pathway or for the DVT Service, departmental guidance	To ensure patient safety and correct management of patients on anticoagulation therapy	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
5. IT system or machine failure		
If the INRstar dosing programme is not available due to IT system failure. Discuss the INR result with anticoagulation lead clinician referring to printed copies of the dosing diary or summary sheet and yellow book.	To ensure patient safety and correct management of patients on anticoagulation therapy	Designated user performing sample taking and/or clinician providing clinical input regarding warfarin dose
Failure of the machine to operate. • Contact Roche Diagnostics Technical Support Line on 0808 100 19 20, they will try to resolve this over the phone. • If the meter is required to be sent in for examination then they will provide you with a loan meter to cover this period. • Within your Warranty period (5 years) if it is a meter fault then it will be replaced free of charge, if it is deemed to be a user fault, for example contamination, then this warranty will not apply.	To ensure patient safety and correct management of patients on anticoagulation therapy	Designated user
Maintenance of the machine As there are no moving parts, no annual maintenance is required, apart from regular Quality Control testing	To ensure patient safety and correct management of patients on	Designated user

	anticoagulation therapy	

EQUALITY ASSESSMENT	During the development of this procedure the Trust has considered the clinical needs of each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation). There is no clinical evidence of exclusion of these named groups. If staff become aware of any clinical exclusions that impact on the delivery of care, this should be reported using the Trust's incident reporting system and an appropriate action plan put in place

TRAINING	
SPECIALIST COMPETENCIES OR QUALIFICATIONS	Refer to the Trust's Training Matrix. All Clinicians providing warfarin management **must complete** BMJ e-learning modules initiating and maintaining anticoagulant therapy available on line at www.learning.bmj.com The anticoagulation lead or designated person must ensure the competence of all staff involved in the use of CoaguChek XS Plus machine and INRstar dosing decision software (where appropriate) and be able to provide evidence of competency
CONTINUING EDUCATION & TRAINING	1. Staff must comply with the Trust's Training Matrix which specifies mandatory training requirements. 2.In addition staff must comply with their service level training matrix for training and competencies as required for role • Completion of training for use of CoaguChek meter and annual updates, competencies • Annual updates in warfarin management and dose decision making • Evidence of training updates to be retained in professional portfolio. 3. All staff to have an annual appraisal
RISK ASSESSMENTS	The service has a responsibility to ensure correct storage and maintenance of the consumables and the CoaguChek XS Plus machine as per manufacturer's instructions
ORGANISATION	Wirral Community NHS Trust
DEPARTMENT (IF APPLICABLE)	Primary and Unplanned Care

Individual Authorisation

Staff involved in the management of patients on anticoagulation therapy named below based at……Service or GP Practice

I have read and understood this Standard Operating Procedure and agree to handle the equipment in accordance with this procedure.

Name of Employee	Signature	Practice Anti-coagulation lead General Practitioner	Date

Appendix 1

Anti-Coagulation Monitoring Form

Answers to these questions will provide information to aid the interpretation of the INR result and guide the clinician when arranging the next appointment.

Have any of your details changed? (Phone no, GP etc)
Have you had any unexplained bruising, bleeding or unusual headaches since your last visit?
Do you, or have you ever suffered with any stomach problems?
Have you varied from the warfarin dose shown in your book (or missed any tablets)?
Have you been unwell, off your food or are you on a special diet?
Have you had any special celebrations or been away on holiday?
Have you had any medication changes, any additions, deletions or dose alterations?
Do you take any herbal or over the counter medicines?
Have you been admitted to hospital since your last clinic visit.
Do you have an admission date for the future?
Are you likely to be unavailable during the next 3 months?